CAS MEDICAL SYSTEMS, INC.

510 / 511

Cardiorespiratory Monitor

Preventative Maintenance Test Procedure

using the 2301Multi-Function Tester

CAS MEDICAL SYSTEMS, INC.
TECHNOLOGY APPLIED TO MEDICINE

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I. Scope

The purpose of this procedure is to provide a means by which a qualified person can perform a Preventative Maintenance Test to a Model 510 or Model 511 Cardiorespiratory Monitor.

II. Maintenance Intervals

CAS Medical Systems, Inc. recommends the following Maintenance Intervals for the Model 510 or Model 511 monitor.

- Preventative Maintenance – In-Between Patients
- Bench Testing – Once every year
- Battery and Audio Indicator Replacement – Every (3) three years (performed at CAS Medical Systems)

III. Equipment Required

To perform this procedure, you will need the following:

- Model 510 or 511 monitor (hereafter referred to as 51X)
- Power Supply Charger (p/n 01-04-0004)
- AC Power Cord (p/n 01-04-0016)
- Model 2301 Multi-Function Tester (p/n 01-05-0025)
- Patient Cable (p/n 01-04-0106)
- Lead Wires (p/n 01-04-0110)
- Stopwatch or equivalent
- Model 510 and 511 Operator's Manual (reference material) (p/n 21-02-0062)
- Model 2301 User's Manual (reference material) (p/n 21-02-0102)

Note: Simulator

This procedure is based on the CAS Medical System's Model 2301 Multi-Function Tester. Should one not be available, a compatible, fully calibrated, simulator with similar settings will be acceptable. The simulator's Make, Model and Calibration Date should be noted on the Data Sheet. The Data Sheet should also be marked with the values that were used during the procedure for each step.

Data Sheet Requirement

This procedure uses a Data Sheet as the record for verifying monitor performance. Once the procedure is completed, CAS recommends the Data Sheet be kept with the respective monitor's Device History Record should verification of monitor performance be questioned.

IV. Initial Setup

A. Connect the (6) six-pin Power Supply Charger connector to its mating receptacle located on the rear panel of the monitor.

B. Connect the power cord to the power input receptacle on the Power Supply Charger. Plug the other end of the power cord into a properly grounded A.C. outlet of the appropriate voltage. Verify the green CHARGING visual indicator located on the front panel of the monitor is lit.

C. Connect the Patient lead wires to the Patient Cable (white to RA; black to LA). Plug the male end of the lead wires into the Simulator (white to white jack; black to black jack).

D. Connect the Patient Cable to the ECG/RESP input receptacle located on the front panel of the monitor.

V. Equipment Setup

1. Simulator Setup

A. Set the switches on the Model 2301 as follows:
   a. LEAD CHANGE = **OFF**
   b. TEST = **SIMULATE/ELECTRODE TEST**
   c. HEART (BPM) = **120 Beats Per Minute**
   d. BREATH (BPM) = **15 Breaths Per Minute**

B. Turn the Simulator “ON”.

C. Once the Simulator has completed its power on sequence, verify one of the following:
   1. If the simulator displays a “1” at the far left of the LCD, the value is meaningless and should be disregarded.
   2. If the simulator displays “BAT” in the upper left corner of the LCD, the 9 Volt battery needs to be replaced.

D. Verify, the red APNEA indicator is not lit.

2. Monitor Setup

A. Power up the monitor.

To power up the monitor, depress the front panel DISPLAY ON/OFF pushbutton switch.

B. Access the Configuration Menus.

To access the Configuration Menus – The LCD Control Panel access door, located on the bottom of the monitor, must be opened to gain access and view the Configuration Menus. Once the monitor is turned "ON" and completes its Initialization, the LCD control panel defaults to a status screen where messages can be viewed. The +, -, and ↵ pushbutton switches are used to enter, exit and make selections within the Configuration Menus provided (Alarm Limits, Setup Menu, and Other). Refer to **Section 3, Configuration Menus** in the **Operator's Manual** for assistance.

C. At PRESS ANY KEY, press any key to enter the Configuration Menus.

D. At ALARM LIMITS, press the + pushbutton switch to select.

NOTE: If the monitor is a Model 510 or if Sibling Protection is enabled, enter the password (+ + - +).

E. Set the APNEA Alarm Limit to **20 SEC**.

F. Set the LOW HEART RATE (LOW HR) Alarm Limit to **40 BPM**.

G. Set the HIGH HEART RATE (HIGH HR) Alarm Limit to **200 BPM**.

H. Set the LOW SPO2 to **88 (%)**.

I. Set the HIGH SPO2 to **96 (%)**. (Model 511 only)

J. Set PB (Periodic Breathing) to **OFF**.

K. Press the – pushbutton switch to EXIT the ALARM LIMITS.

L. Press the ↵ pushbutton switch and select the SETUP MENU.

M. At SETUP MENU, press the + pushbutton switch to select.

NOTE: If the monitor is a Model 510 or if Sibling Protection is enabled, enter the password (- + - -).

N. Set the ALARM VOLUME to **1**.

O. Set the QRS VOLUME to **1**. (Model 511 only)

P. Set the PATIENT MODE to **INFANT**.

Q. At CLEAR MEMORY, press the + TO SELECT pushbutton switch.

R. Set the DATE/TIME to the current **Day, Month, Year, Hour and Minute**.

S. If the unit has a Memory Card installed, set the ECG Trace Storage to **OFF**.

T. If the unit has a Memory Card installed, set the SPO2 Trace Storage to **OFF**.

U. If the unit has a Memory Card installed, set the Auxiliary Trace Storage to **OFF**.

V. Set the ID Number to **000001234**.

W. Press the – pushbutton switch to EXIT the SETUP MENU.

X. Turn the Model 51X monitor "OFF".

NOTE: If Sibling Protection is not enabled - Press the front panel DISPLAY ON/OFF pushbutton.

If the monitor is a Model 510 or if Sibling Protection is enabled - Press and hold the RESET (RESET/MUTE) pushbutton for at least (3) three seconds, continue to hold the pushbutton, and then push the DISPLAY ON/OFF pushbutton.

VI. Preventative Maintenance Test

1. Functional Test

1.1 High Heart Rate Alarm Test

A. Turn "ON" the monitor by pressing the front panel **DISPLAY ON/OFF** pushbutton. Verify the green visual indicator next to the DISPLAY ON/OFF pushbutton switch is lit.

B. Once the monitor has completed its power up sequence, verify the HEART RATE and RESPIRATION visual indicators are flashing at the rates set on the simulator with no Human Alarm visual indicators or audible alarms active. If the monitor is a Model 511, verify 1) the numeric values for HEART RATE and RESPIRATION are correct and 2) an audible "beep" is heard with each heartbeat.

C. Set the simulator HEART Rate to **240 BPM**. Verify, the monitor's HEART RATE **HIGH** visual indicator and audible alarm activate. If the monitor is a Model 511, also verify the HEART RATE numeric value is flashing.

D. Set the simulator HEART Rate to **120 BPM**. Verify, the monitor audible alarm silences and the HEART RATE **HIGH** visual indicator remains on. If the monitor is a Model 511, also verify the HEART RATE numeric value is no longer flashing.

E. Press the RESET (RESET/MUTE) pushbutton switch on the monitor. Verify, the **HIGH** visual indicator clears and the HEART RATE and RESPIRATION indicators are flashing at the rates set on the simulator.

Proceed to Low Heart Rate Alarm Test.

1.2 Low Heart Rate Alarm Test

A. Set the simulator HEART Rate to **30 BPM**. Verify, the monitor's HEART RATE **LOW** visual indicator and audible alarm activate. If the monitor is a Model 511, also verify the HEART RATE numeric value is flashing.

B. Set the simulator HEART Rate to **60 BPM**. Verify, the monitor audible alarm silences and the HEART RATE **LOW** visual indicator remains on. If the monitor is a Model 511, also verify the HEART RATE numeric value is no longer flashing.

C. Press the RESET (RESET/MUTE) pushbutton switch on the monitor. Verify, the **LOW** visual indicator clears and the HEART RATE and RESPIRATION indicators are flashing at the rates set on the simulator.

Proceed to Apnea Alarm Test.

1.3 Apnea Alarm Test

A. Press the **APNEA** button on the simulator. Verify,

1) the red APNEA indicator on the simulator is lit.
2) Begin timing for apnea with the last Respiration pulse. Stop timing when the monitor's **APNEA** visual and audio alarm activates. Verify, the time is 20 +/- 1.0 seconds. If the monitor is a Model 511, also verify the RESPIRATION numeric value is flashing.

B. Press the **APNEA** button on the simulator. Verify, 1) the red APNEA indicator on the simulator is not lit 2) the RESPIRATION indicator is flashing at the rate set on the simulator 3) the monitor audible alarm silences and 4) the **APNEA** visual indicator on the monitor remains on. If the monitor is a Model 511, also verify the RESPIRATION numeric value is no longer flashing.

C. Press the RESET (RESET/MUTE) pushbutton switch on the monitor. Verify, the **APNEA** visual indicator clears and the HEART RATE and RESPIRATION indicators are flashing at the rates set on the simulator.

Proceed to Heart Beat = Respiration Test.

1.4 Heart Rate = Respiration Test

A. Set the simulator to the following settings:

a. Set the HEART Rate to **60 BPM**.
b. Set the BREATH Rate to **60 BrPM**.

B. Verify, 1) the HEART RATE indicator continues to flash at the rate set on the simulator 2) the RESPIRATION indicator is no longer flashing and 3) the monitor audible alarm and **APNEA** visual indicator are activated after 20 seconds. If the monitor is a Model 511, also verify the RESPIRATION numeric value is flashing.

C. Set the simulator BREATH Rate to **40 BrPM**. Verify, 1) the monitor audible alarm silences 2) the HEART RATE and RESPIRATION indicators are flashing at the rates set on the simulator and 3) the **APNEA** visual indicator remains on. If the monitor is a Model 511, also verify the RESPIRATION numeric value is no longer flashing.

D. Press the RESET (RESET/MUTE) pushbutton switch on the monitor. Verify, the **APNEA** visual indicator clears and the HEART RATE and RESPIRATION indicators are flashing at the rates set on the simulator.

Proceed to the Lead Off Alarm Test.

1.5 Lead Off Alarm Test

A. Disconnect a lead wire from the simulator. Verify, 1) the HEART RATE and RESPIRATION indicators are no longer flashing and 2) the monitor **LEAD OFF** visual indicator and audible alarm activate. If the monitor is a Model 511, verify both the HEART RATE and RESPIRATION numeric values indicate dashes (---).

B. Reconnect the lead wire to the simulator. Verify, 1) the monitor audible alarm silences 2) the HEART RATE and RESPIRATION indicators are flashing at the rates set on the simulator and 3) the **LEAD OFF** visual indicator remains on. If the monitor is a Model 511, verify the HEART RATE and RESPIRATION numeric values are correctly displayed.

C. Press the RESET (RESET/MUTE) pushbutton switch on the monitor. Verify, the **LEAD OFF** visual indicator clears and the HEART RATE and RESPIRATION indicators are flashing at the rates set on the simulator.

Proceed to Respiration Rate Test.

1.6 Respiration Rate Test

A. Set the simulator to the following settings:

   a. Set the HEART Rate to **120 BPM**.

   b. Set the BREATH Rate to **15 BrPM**.

B. Verify the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.

C. Set the BREATH Rate to **40 BrPM**. Verify the HEART RATE and RESPIRATION indicators are flashing at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.

D. Set the BREATH Rate to **60 BrPM**. Verify the HEART RATE and RESPIRATION indicators are flashing at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.

E. Set the BREATH Rate to **80 BrPM**. Verify the HEART RATE and RESPIRATION indicators are flashing at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.

Proceed to Improper Shutoff Test.

1.7 Improper Shutoff Test (Sibling Protection Alarm) Model 510 or Model 511 if enabled

A. Depress the front panel DISPLAY ON/OFF pushbutton switch. Verify, 1) all the front panel visual indicators are turned "ON" 2) an audible alarm is active. If the monitor is a Model 511, also verify the HEART RATE numerics indicate "888", the RESPIRATION and %SpO_2 (if installed) numerics indicate "188".

B. Depress the DISPLAY ON/OFF pushbutton switch. Verify, 1) the audible alarm silences and 2) the monitor performs a reset and continues to count at the rates set on the simulator.

C. Turn the monitor "OFF".

Turn the simulator "OFF". Disconnect the simulator from the monitor.

This concludes the Model 510 / 511 Preventative Maintenance Test Procedure.

Should you have any questions, do not hesitate to contact CAS Technical Support at 203-488-6056 / 800-227-4414 (US only) (phone), 203-488-9438 (fax) or www.techsrv@casmed.com (email).

Date: _____

Tested By: _____

VII. Test Data Sheet

510 / 511 Monitor

using the 2301 Multi-Function Tester

Home Care Dealer / Hospital: _____

Address: _____

City: _____

State: _____ Zip: _____

Monitor Type: (select one) 510 ( ) ; 511 ( )

Monitor Serial Number: _____

Simulator Type / Serial Number: _____

Simulator Calibration Date: _____

IV. Initial Setup

A.	Connect the (6) six-pin charger cord to the monitor.	Completed ( )
B.	Connect the power cord to the Power Supply Charger. Verify, green CHARGING indicator is lit.	Pass ( ) Fail ( )
C.	Connect the Patient lead wires to the Patient Cable and Simulator.	Completed ( )
D.	Connect the Patient Cable to the ECG/RESP input on the monitor.	Completed ( )

V. Equipment Setup

1. Simulator Setup

A.	Set the switches on the 2301 simulator:	
a.	LEAD CHANGE = OFF	Completed ( )
b.	TEST = SIMULATE/ELECTRODE TEST	Completed ( )
c.	HEART (BPM) = 120	Completed ( )
d.	BREATH (BPM) = 15	Completed ( )
B.	Turn the simulator ON.	Completed ( )
C.	Verify one of the following conditions:	
1.	Simulator displays a “1” at the far left of the LCD display	Pass ( ) Fail ( )
2.	Simulator displays “BAT” in the upper left corner of the LCD display	Pass ( ) Fail ( )
D.	Verify, the red APNEA indicator is not lit	Pass ( ) Fail ( )

2. Monitor Setup

A.	Power up the monitor.	Completed ( )
B.	Access the Configuration Menus.	Completed ( )
C.	At PRESS ANY KEY, press any key to enter the Configuration Menus.	Completed ( )
D.	At ALARM LIMITS, press the + pushbutton switch to select.	Completed ( )
E.	Set the APNEA Alarm Limit to 20 SEC.	Completed ( )
F.	Set the LOW HR Alarm Limit to 40 BPM.	Completed ( )
G.	Set the HIGH HR Alarm Limit to 200 BPM.	Completed ( )
H.	Set the LOW SPO2 to 88.	Completed ( )

I.	Set the HIGH SPO2 to 96. (511 only)	Completed ( )
J.	Set the PB to OFF.	Completed ( )
K.	Press the – pushbutton switch to EXIT the ALARM LIMITS.	Completed ( )
L.	Press the ↵ pushbutton switch and select the SETUP MENU.	Completed ( )
M.	At SETUP MENU, press the + pushbutton switch to select.	Completed ( )
N.	Set the ALARM VOLUME to 1.	Completed ( )
O.	Set the QRS VOLUME to 1.	Completed ( )
P.	Set the PATIENT MODE to INFANT.	Completed ( )
Q.	At CLEAR MEMORY, press the + TO SELECT pushbutton switch.	Completed ( )
R.	Set the DATE/TIME to the current Day, Month, Year, Hour, and Minute.	Completed ( )
S.	If the unit has a Memory Card installed, set the ECG Trace Storage to OFF.	Completed ( )
T.	If the unit has a Memory Card installed, set the SPO2 Trace Storage to OFF.	Completed ( )
U.	If the unit has a Memory Card installed, set the Auxiliary Trace Storage to OFF.	Completed ( )
V.	Set the ID Number to 000001234.	Completed ( )
W.	Press the – pushbutton switch to EXIT the SETUP MENU.	Completed ( )
X.	Turn the Model 51X monitor “OFF”.	Completed ( )

VI. Preventative Maintenance Test

1. Functional Test

1.1 High Heart Rate Alarm Test

A.	Turn the monitor “ON”. Verify the visual indicator is lit.	Pass ( )	Fail ( )
B.	Verify, monitor counts rates set on simulator with no alarms.	Pass ( )	Fail ( )
	For Model 511, verify		
	1) the numeric values for HEART RATE and RESPIRATION are correct.	Pass ( )	Fail ( )
	2) an audible “beep” is heard with each heartbeat.	Pass ( )	Fail ( )
C.	Set the simulator HEART Rate to 240. Verify, HIGH visual and audible alarms.	Pass ( )	Fail ( )
	For Model 511 – Verify, HEART RATE numeric value is flashing.	Pass ( )	Fail ( )
D.	Set the simulator HEART Rate to 120. Verify, audible stops and HIGH visual remains on.	Pass ( )	Fail ( )
	For Model 511 – Verify, HEART RATE numeric value is no longer flashing.	Pass ( )	Fail ( )
E.	Press RESET. Verify, HIGH visual clears and monitor counts rates set on simulator.	Pass ( )	Fail ( )

1.2 Low Heart Rate Alarm Test

A.	Set the simulator HEART Rate to 30. Verify, LOW visual and audible alarms.	Pass ( )	Fail ( )
	For Model 511 – Verify, HEART RATE numeric value is flashing.	Pass ( )	Fail ( )
B.	Set the simulator HEART Rate to 60. Verify, audible stops and LOW visual remains on.	Pass ( )	Fail ( )
	For Model 511 – Verify, HEART RATE numeric value is no longer flashing.	Pass ( )	Fail ( )
C.	Press RESET. Verify, LOW visual clears and monitor counts rates set on simulator.	Pass ( )	Fail ( )

1.3 Apnea Alarm Test

A. Press the APNEA button on the simulator and verify,
   1) the red APNEA indicator on the simulator is lit. Pass ( ) Fail ( )
   2) Verify, the time to be 20 +/- 1.0 seconds. Pass ( ) Fail ( )

   For Model 511 – Verify, RESPIRATION numeric value is flashing. Pass ( ) Fail ( )

B. Press the APNEA button on the simulator. Verify,
   1) the red APNEA indicator on the simulator is not lit. Pass ( ) Fail ( )
   2) the RESPIRATION indicator is flashing at rate set on simulator. Pass ( ) Fail ( )
   3) the audible stops. Pass ( ) Fail ( )
   4) the APNEA visual remains on. Pass ( ) Fail ( )

   For Model 511 – Verify, RESPIRATION numeric value is no longer flashing. Pass ( ) Fail ( )

C. Press RESET on monitor. Verify, APNEA visual clears and monitor counts rates set on simulator. Pass ( ) Fail ( )

1.4 Heart Rate = Respiration Test

A. Set the simulator to the following settings:
   a. Set the HEART Rate to 60. Completed ( )
   b. Set the BREATH Rate to 60. Completed ( )

B. Verify,
   1) the HEART RATE indicator continues to flash at the rate set on the simulator. Pass ( ) Fail ( )
   2) the RESPIRATION indicator is no longer flashing. Pass ( ) Fail ( )
   3) the monitor audible alarm and APNEA visual indicator are activated after 20 seconds. Pass ( ) Fail ( )

   For Model 511 – Verify, RESPIRATION numeric value is flashing. Pass ( ) Fail ( )

C. Set the simulator BREATH Rate to 40. Verify,
   1) the monitor audible alarm silences. Pass ( ) Fail ( )
   2) the HEART RATE and RESPIRATION indicators flash at the rates set on the simulator. Pass ( ) Fail ( )
   3) the APNEA visual indicator remains on. Pass ( ) Fail ( )

   For Model 511 – Verify, RESPIRATION numeric value is no longer flashing. Pass ( ) Fail ( )

D. Press RESET. Verify, APNEA visual clears and the monitor counts rates set on simulator. Pass ( ) Fail ( )

1.5 Lead Off Alarm Test

A. Disconnect a lead wire from the simulator. Verify,
   1) the HEART RATE and RESPIRATION indicators are no longer flashing. Pass ( ) Fail ( )
   2) LEAD OFF visual and audible alarms. Pass ( ) Fail ( )

   For Model 511 – Verify, HEART RATE and RESPIRATION numeric values are dashes (---). Pass ( ) Fail ( )

B. Reconnect the lead wire to the simulator. Verify,
   1) audible alarm silences. Pass ( ) Fail ( )
   2) the HEART RATE and RESPIRATION indicators flash at the rates set on the simulator. Pass ( ) Fail ( )
   3) LEAD OFF visual remains on. Pass ( ) Fail ( )

   For Model 511 – Verify, both numeric values are correctly displayed. Pass ( ) Fail ( )

C. Press RESET. Verify, LEAD OFF visual clears and monitor counts rates set on simulator. Pass ( ) Fail ( )

1.6 Respiration Response Test

A. Set the simulator to the following settings:
   a. Set the HEART Rate to 120. Completed ( )
   b. Set the BREATH Rate to 15. Completed ( )

B. Verify, monitor counts rates set on simulator with no alarms. Pass ( ) Fail ( )

C. Set the BREATH Rate to 40. Verify, the monitor counts rate set on simulator with no alarms. Pass ( ) Fail ( )

D. Set the BREATH Rate to 60. Verify, the monitor counts rate set on simulator with no alarms. Pass ( ) Fail ( )

E. Set the BREATH Rate to 80. Verify, the monitor counts rate set on simulator with no alarms. Pass ( ) Fail ( )

1.7 Improper Shutoff Test (Sibling Protection Alarm)

A. Depress the front panel DISPLAY ON/OFF pushbutton switch. Verify,
   1) all front panel visual indicators are turned “ON”. Pass ( ) Fail ( )
   2) an audible alarm is active. Pass ( ) Fail ( )
   For Model 511 – HEART RATE numerics = 888, RESPIRATION and % SpO2 (if installed) numerics = 188. Pass ( ) Fail ( )

B. Depress the DISPLAY ON/OFF pushbutton switch. Verify,
   1) the audible alarm silences. Pass ( ) Fail ( )
   2) the monitor performs a reset and continues to count at the rates set on the simulator. Pass ( ) Fail ( )

C. Turn the monitor “OFF”. Pass ( ) Fail ( )

If the monitor fails to pass any part of this procedure, please return a copy of this Data Sheet with the monitor when it is returned for service.

Comments: _____

_____

_____

_____

This concludes the Model 510 / 511 Test Data Sheet.

VIII. Certification Acknowledgement Sign-Off Sheet

Home Care Dealer / Hospital: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____ Fax Phone: _____

By signing below, I have read and understood the Model 510 / 511 Preventative Maintenance Test Procedure and agree to adhere to it using the equipment required to the best of my ability.

Print Name, as it would appear on the certificate of the individual being certified:

_____

Signature: _____ Date: _____

Email Address: _____

Would you like to be contacted concerning any product updates / improvements? Yes ( ) No ( )

Once completed, keep a copy for your records and mail the original sign-off sheet to:

CAS Medical Systems, Inc.
44 E. Industrial Rd
Branford, CT 06405
U.S.A.

203-488-6056 / 800-227-4414 (US only)(phone)
203-488-9438 (fax)
www.casmed.com

ATTN: Product Support Manager

This Sign-Off Sheet may be copied if additional individuals will be certified.